REMARKS

Applicant notes with appreciation that claims 7-15 and 20-24 are allowed.

Claims 1-25 were previously pending in this application. By this amendment, Applicant is canceling claim 25 without prejudice or disclaimer. As a result claims 1-24 are pending for examination with claims 1, 7, 10, 16 and 20 being independent claims. No new matter has been added.

Rejections Under 35 U.S.C. §103

The Examiner rejected claims 1-6, 16-19 and 25 under 35 U.S.C. §103(a) as being unpatentable over the combination of Wieland in view of Vasankari. Claim 25 has been canceled and therefore is not addressed further with respect to this rejection. Applicant traverses the rejection of claims 1-6 and 16-19 for the following reasons.

The claimed invention

The claimed kits are used in procedures to screen for atherosclerosis and coronary heart disease (claims 1-6), or to quantify oxidation parameters of lipids in a LDL fraction (claims 16-19) by isolating a LDL lipid fraction.

The kit of claim 1 includes two containers that contain (1) a reagent for isolating LDL from a serum or plasma sample for the preparation of a LDL fraction, and (2) a reagent for separating the lipids from the LDL fraction.

The kit of claim 16 includes two containers that contain (1) containing a solvent which extracts lipids from a LDL fraction; and (2) an amount of resuspension solvent sufficient to resuspend the extracted lipids.

The prior art

According to the Examiner, Wieland teaches that LDLs can be selectively precipitated using heparin. The Examiner also stated that Wieland teaches that LDL lipids can be determined by various techniques after selective precipitation, in particular at page 904, column 2. Wieland only teaches that cholesterol can be determined using an enzymatic procedure (see page 905, left

[illegible] to generate a colored product that can be read spectrophotometrically. Moreover, Wieland does not suggest extraction of lipids from LDLs as is performed using the instant

invention. Therefore, Wieland lacks any mention or suggestion of solvent extraction to isolate lipids from LDL.

According to the Examiner, Vasankari teaches extracting lipids from serum samples using a chloroform:methanol solvent followed by cyclohexane. The Examiner also indicated that "where the lipids are extracted from is not critical to the invention." Office Action at page 5. Applicant respectfully disagrees; the claims are clear that the kits are used for separating lipids from the LDL fraction, not from some other fraction of serum or from whole serum, as performed by Vasankari. In any event, Vasankari certainly lacks any suggestion to apply the solvent extraction to fractions of serum, such as LDLs.

The combination of the prior art, even if proper, does not teach or suggest the claimed invention

Considering the cited references together, the combined teachings of Wieland and Vasankari do not teach or suggest the claimed kits that contain the reagents necessary for screening for atherosclerosis and coronary heart disease, or for quantifying oxidation parameters of lipids in a LDL fraction.

Wieland isolates LDLs from serum, as noted above. Following the procedure of Wieland would yield an LDL fraction as a precipitate, and a supernatant that contains serum minus the LDLs. Vasankari teaches that lipids can be extracted from serum. Therefore, applying the method of Vasankari to the product of the Wieland precipitation reaction, one of ordinary skill in the art would extract the supernatant, not the precipitated LDLs, because Vasankari does not teach or suggest the use of the extraction method on a precipitated fraction of serum. Thus, the combination of Wieland and Vasankari would result in the recovery of lipids from everything except LDLs. Therefore, the combination of the cited references does not provide the elements of the claimed invention.

In fact, given that Vasankari teaches extraction of lipids from whole serum, not fractions thereof, Vasankari teaches away from the combination of the references

Moreover, Wieland also teaches away from any combination with Vasankari, because Wieland teaches that cholesterol should be determined using an enzymatic procedure, and therefore there would be no need for solvent extraction in order to extract lipids from the LDLs

[illegible] other reference to include a reagent for use in the determination of the [illegible]

level of conjugated dienes (LDL-BDC) in the lipid fraction. Therefore, at the very least, claims containing this limitation should be allowable over the cited prior art.

There is no motivation to combine the cited prior art

The Examiner has stated that one of ordinary skill in the art would have been motivated to use the method of Vasankari to extract lipids from the LDL precipitated according to the method of Wieland because "there are a number of known methods of extracting the lipid fraction and any of the known methods would have the expected result. To select the methods of Vasankari would have been obvious because it would have the expected result." Office Action at page 4.

Applicant respectfully disagrees that this is a sufficient motivation for one of ordinary skill in the art to have combined the cited references.

First, Wieland teaches that simply obtaining LDL is sufficient for analysis and therefore one of ordinary skill in the art would have no reason to extract lipids from LDL.

Second, even assuming that one of ordinary skill in the art was motivated to extract lipids from LDLs as isolated by Wieland, the Examiner supplies no reason for selecting the particular method of Vasankari, other than that "it would have the expected result." However, the Examiner's own reasons argue against the sufficiency of the motivation, because "any of the known methods [of lipid extraction] would have the expected result." (emphasis added) Therefore, as there is no specific reason for selecting the particular lipid extraction method of Vasankari provided by either the Vasankari reference or the Wieland reference, the specific combination appears to have been made with Applicant's invention in mind, i.e., with impermissible hindsight. The mere description of a particular method by a reference does not provide a motivation to combined the reference with another reference in a combination for an obviousness rejection. The Examiner must provide a basis for making the combination that is recognized in the law; this has not been done.

Third, as noted above, Wieland teaches away from the use of the solvent extraction method of Vasankari. Wieland teaches that cholesterol can be analyzed by an enzymatic procedure using a commercial test kit (see page 905, left column). Therefore, Wieland does not

Therefore, in view of the foregoing arguments, the combination of the Wieland reference and the Vasankari reference do not provide the elements of the claimed invention, and/or the combination is improper for a lack of motivation to combine the references. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of claims 1-6 and 16-19 under 35 U.S.C. 103(a).

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

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